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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,438	11/20/2001	William Stefan Bess	5724-03-EJF	3857

7590 10/03/2003
Evan J. Federman
Legal Division, Warner-Lambert Company
201 Tabor Road
Morris Plains, NJ 07950

EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/03/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,438

Applicant(s)

BESS ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,32-34,36-38,40 and 42-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,32-34,36-38,40 and 42-49 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1, 32-34, 36-38,40 and 42-49 are pending.
2. Claims 1, 32-34, 36-38,40 and 42-49 are rejected.

Response to Arguments

3. Applicants' arguments filed June 24, 2003 have been fully considered but they are not persuasive with respect to Nichols et al. of WO 97/37689 as well as Keown et al. of WO 95/11034. Applicants allege that neither Keown et al. nor Nichols et al. disclose the claimed embodiments of Applicants invention.

4. Applicants allege that Keown et al. do not disclose the claimed embodiments of Applicants invention. The following reasons dispute this argument. Keown et al. teach of a pharmaceutical composition which contains a sympathomimetic agent, such as ephedrine, and a mineral cation salt, namely chromium, (as cited from the abstract). In addition, Keown et al. also teach that this pharmaceutical composition contains various semipermeable polymers that are known in the art such as those of, inter alia, U.S. Patent No. 3,546,142, (as cited on page 15 of Keown et al.). U.S. Patent No. 3,546,142 lists the amine-containing polymer of polydimethylaminoethyl methacrylate, (see column 2, lines 13-14). Accordingly, Keown et al. again render the instant composition claims obvious because the skilled artisan would have been motivated to select a known material based on its suitability for its intended use, which supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S.

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327, 65 USPQ 297 (1945). In addition, composition claims are not deemed to be limited by an "intended use", see *In re Hack* 114 USPQ 161. Accordingly, the prior art reference of Keown et al. do render the instant invention obvious because Keown et al. of a sympathomimetic amine, namely ephedrine, and Keown et al. teach of the presence of the transition metal of chromium. Furthermore, applicants recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

5. Applicants allege that Keown et al. do not disclose the claimed embodiments of Applicants invention. The following reasons dispute this argument. Nichols et al. teach of a composition that contains a sympathomimetic amine with other compounds, which make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds, (see page 4, lines 1-23). In addition, Nichols et al. teach of various denaturants, in particular amine-containing compounds and well as various polymers, that are used to make the pure sympathomimetic amine salt difficult or essentially infeasible to isolate. Nichols et al. also teach and provide explicit motivation to include other components such as "acrylic derivatives", (see page, lines 20-23). In view of this information, the skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of carriers and excipients and conventional ingredients that would render the instant invention obvious. Furthermore, applicants recite the word "comprising", which is open-claim language. It is held that

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“the word ‘comprising’ incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim”. *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

Claim Objections

6. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

7. Misnumbered claims 2-4, 36-38, 49, and 42-49 have been renumbered as claims 32-34, 36-38, 40 and 42-49, respectively.

Information Disclosure Statement

8. The Information disclosure statement filed on July 28, 2003 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Claim 36 has dependency on cancelled claim 35, which renders the claim vague and indefinite.

11. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 has dependency on cancelled claim 39, which renders the claim vague and indefinite.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. The rejection of claims 1, 32-34, 36-38,40 and 42-49 under 35 U.S.C. 103 as being unpatentable over Keown et al. of WO 95/11034 is maintained for both the above-stated and reasons of record.

14. Claims 1, 32-34, 36-38,40 and 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. of WO 97/37689. Nichols et al. teach of a composition that contains a sympathomimetic amine with other compounds, which make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds, (see page 4, lines 1-23). In addition, Nichols et al. teach of various denaturants, in particular amine-containing compounds and well as various polymers, that are used to make the pure sympathomimetic amine salt difficult or essentially infeasible to isolate. Nichols et al. do not specifically teach of an amino

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polymer. The skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of denaturants, especially when Nichols et al. teach of various denaturants, in particular amine-containing compounds and various types of polymer-containing compounds because the purpose of the denaturant is to make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds.

Obviousness-type Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. The rejection of claims 1 and 32-34, 36-38, 40 and 42-49 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. U.S. Patent No. 6,359,011 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to salts of transition metals whereas

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U.S. Patent No. U.S. Patent No. 6,359,011 is directed to transition metal salts of iron, copper, cobalt, manganese, nickel and zinc.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

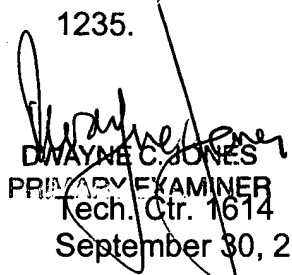
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
September 30, 2003